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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,092	12/05/2001	Yinghong Yu	13569.0018US01	8563

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EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,092	YU ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-76 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,2,6-12,15-23,25,27,28,32-38,41-49,52,53,57-63 and 66-74 is/are rejected.

7)☒ Claim(s) 3-5,13,14,24,26,29-31,39,40,50,51,54-56,64,65,75 and 76 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 05 December 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/21/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 11, 12, 15, 17, 27, 37, 38, 41, 43, 52, 62, 63, 66 and 68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7, 13 and 15-17 of copending Application No. 10/236,714. Although the conflicting claims are not identical, they are not patentably distinct from each other because present claim 1 is merely a broader version of the subject matter covered by claims 13 and 15 presented in the '714 application. Likewise, claims 27 and 52 of the present application is merely a broader version of the subject matter covered by claims 4 and 7, or 16 and 17, presented in the '714 application. Assuming the '714 invention receives a patent, the applicant would not be entitled to receive a patent for the generic or broader invention (*In re Goodman*, 11 F. 3d 1046, 29 USPQ 2d 2010 (Fed. Cir. 1993)).

Regarding claims with limitations of the type found in claims 11 and 12, those of ordinary skill in the art would have seen the particular landmark or fiducial points from which to base phase difference measurement to be a matter of obvious design. Clearly any recurrent feature of the waveform signifying a contraction such as the onset of

contraction or the peak of a contraction signal could have been used as long as the point selection was consistently applied from one accelerometer output to the other.

Regarding claim 15 and claims with similar limitations, the examiner considers it inherent that an accelerometer continuously senses motion during consecutive cardiac cycles by virtue of the fact that the piezoelectric material will by its physical nature produce an electrical signal indicative of motion any time the heart contracts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1, 2, 6-12, 15-22, 27, 28, 32-38, 41-48, 53, 57-63 and 66-73 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/206,131. Although the conflicting claims are not identical, they are not patentably distinct from each other because present claim 1 is merely a broader version of the subject matter covered by claims 10-18 presented in the '131 application. Likewise, claims 27 and 52 of the present application is merely a broader version of the subject matter covered by claims 1-9, presented in the '131 application. Assuming the '131 invention receives a patent, the applicant would not be entitled to receive a patent for the generic or broader invention (*In re Goodman*, 11 F. 3d 1046, 29 USPQ 2d 2010 (Fed. Cir. 1993)).

Regarding claims with limitations of the type found in claims 11 and 12, those of ordinary skill in the art would have seen the particular landmark or fiducial points from which to base phase difference measurement to be a matter of obvious design. Clearly any recurrent feature of the waveform signifying a contraction such as the onset of contraction or the peak of a contraction signal could have been used as long as the point selection was consistently applied from one accelerometer output to the other.

Regarding claim 15 and claims with similar limitations, the examiner considers it inherent that an accelerometer continuously senses motion during consecutive cardiac cycles by virtue of the fact that the piezoelectric material will by its physical nature produce an electrical signal indicative of motion any time the heart contracts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 16, 25, 42, 43, 67 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Reference to "...the free wall..." and "...the anterior wall..." in claim 16 lacks antecedence.

The dependency of claim 25 appears to be in error because the reference to a third signal lacks antecedent basis. It is unclear if the applicants intended to recite dependency on claim 23 or 24.

In claims 42 and 43, "...the output module..." lacks antecedent basis. When analyzing the claims on the merits, the examiner will assume that it was the applicants' intent to recite dependency on claim 28. Clarification is requested.

The reference to the stimulation means in claims 67 and 68 lacks antecedent basis.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 15-17, 23, 27, 41, 49, 52, 66-68 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Moberg et al. (Pat. No. 5,496,361).

Concerning claims 1, 27 and 52, note in particular col. 18, lines 3-11. It should further be noted that the terms "...a first ventricular wall location..." and "...a second

ventricular wall location..." do not necessarily restrict the device to placement about different ventricular chamber walls of the heart, such as the right and the left, but merely different locations (some of which may be on the same wall).

Specifically regarding method claim 1, while the preamble was considered, it was deemed insufficient to distinguish over the Moberg et al. reference absent any step in the body of the claim pertaining to actually synchronizing a contraction based on the comparing step.

Regarding claims 15, 41 and 66, the examiner considers it inherent that the accelerometer of Moberg et al. continuously senses motion during consecutive cardiac cycles by virtue of the fact that the piezoelectric material will by its physical nature produce an electrical signal indicative of motion any time the heart contracts.

Concerning claims 16 and 67, Moberg et al. teach that the leads may be placed in a wide variety of locations and can be accompanied by pacing electrodes for stimulation. By its very nature, a pacing pulse, if successful, evokes contraction of the heart. Therefore a pacing pulse applied to the apex of the right ventricle, for example, will inherently cause contraction of a free wall and an anterior wall.

Regarding claims 23, 49 and 74, see Fig. 6.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 11, 12, 37, 38, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moberg et al. (Pat. No. 5,496,361).

Regarding claims with limitations of the type found in claims 11 and 12, those of ordinary skill in the art would have seen the particular landmark or fiducial points from which to base phase difference measurement to be a matter of obvious design. Clearly

any recurrent feature of the waveform signifying a contraction such as the onset of contraction or the peak of a contraction signal could have been used as long as the point selection was consistently applied from one accelerometer output to the other.

Allowable Subject Matter

10. Claims 2-10, 13, 14, 18-22, 24, 26, 28-36, 39, 40, 44-48, 50, 51, 53-61, 64, 65, 69-73, 75 and 76 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims (in the above listing, the allowance of claims 2, 6-10, 18-22, 28, 32-36, 44-48, 53, 57-61 and 69-73 further requires the submission of an acceptable Terminal Disclaimer).

Regarding claim 2 and claims with similar limitations, there does not appear to be a teaching in the prior art of record for incorporating a step for determining, based on the detected difference in synchronization of a first ventricular wall location contraction and a second ventricular wall location contraction, a parameter for a stimulation pulse. Moberg et al. disclose that the detected difference may be useful in filtering out body motion artifact, but do not discuss changing a pulse parameter based on this difference.

Concerning claims 18-22 and claims with similar limitations, it appears that the device of Moberg et al. determines the difference in synchronization or phase between accelerometers on the same wall of the heart such as between sensors on any one given electrode carrier such as the epicardial patch shown in Fig. 6. Although Fig. 20 shows epicardial patches on the free walls of the right and left ventricles (claim 22), there does not appear to be a teaching to compare the signals between the two patches, but rather a teaching to compare the signals detected at accelerometers of the same electrode patch.

Claims 16, 25, 42/28 and 43/28 upon the acceptance of a Terminal Disclaimer obviating the double patenting rejection, would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Concerning claims 42 and 43, note the comments made above in the rejection of said claims under 35 USC §112.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
May 16, 2004

KENNEDY SCHAETZLE
PRIMARY EXAMINER